



901 E. 233rd Street
Carson, California
90745-6204
310/835-8400
Fax 310/835-6612
NOV 23 2004

November 19, 2004

Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810),
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Brush Pkwy.
College Park, MD 20740

Section 403(r) (6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r) (6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

Menopausal Nutritional Support and Comfort

Black Cohosh may help normalize menstrual cycles of women in childbearing years. It may also offset the decline in estrogen and help balance hormone levels in women. Clinical studies have shown that black cohosh can help relieve menopausal symptoms such as hot flashes and night sweats.

on the following product:

Your Life® Black Cohosh 40 mg

Very truly yours,

Leiner Health Products


A handwritten signature in cursive script that reads 'Kristi Ansnes'.

Kristi Ansnes
Regulatory Affairs Associate

975 0162

LET

14950



Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810),
Center for Food Safety and Applied Nutrition
Food and Drug Administration
(Continued)

The following brands also use the above statement:

Albertson's
BI-MART
BIO BALANCE®
COUNCIL LABS®
CVS®
ECKERD®
equate®
Hannaford®
HealthLine
health PRIDE
Kash n' Karry
KIRKLAND Signature™
Kroger®
Longs
MARC'S
Member's Mark
MEIJER™

Nature's Origin®
NATURE'S VALLEY™
NATURITE®
NUTRA CHOICE
NUTRI-BLEND
Oscor®
PHARMACIST FORMULA®
BODYCOLOGY™
SAFEWAY SELECT™
Sav•on™
Shaw's
ShopKo®
Spring Valley®
TARGET®
TOP CARE®
TRUNATURE®
Wegmans®